ORIGINAL RESEARCH

Skin Tightening Following Multisource, Phase-controlled Radiofrequency Treatments with Novel Unique Concentric Electrodes in Asian Patients

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ABSTRACT

Background: Radiofrequency energy has been shown to penetrate deeper into the skin, independent of skin color, and to be beneficial for skin tightening. It was previously reported that multisource, phase-controlled radiofrequency treatments provide safe and effective skin tightening and rejuvenation. The present study evaluated the effectiveness of multisource, phase-controlled radiofrequency treatments with a unique concentric electrode configuration for skin tightening. **Methods:** Twenty-five Japanese patients were treated with the novel multisource phase-controlled radiofrequency system. Digital photographs and three-dimensional imaging were used to evaluate the results. The patients also provided subjective assessments. **Results:** Objective assessments with digital photographs and superimposed three-dimensional color images showed significant volumetric reduction in the treated areas. Ninety-six percent of patients reported satisfaction with the results, and all patients reported satisfaction with the convenience of the procedure. Complications were minor and transitory, consisting of a slight burning sensation and mild erythema, which resolved within one hour of treatment. No side effects were observed. **Conclusions:** The multisource phase-controlled radiofrequency treatments evaluated in this study showed efficacy with minimal discomfort and side effects. Repeated treatments using this method can provide an alternative to more invasive tightening treatments.

KEYWORDS: Multisource, phase-controlled radiofrequency, skin tightening, volumetric reduction

Demand for a noninvasive and long-lasting treatment to reduce undesirable fat tissue and to induce skin tightening has grown dramatically over the past few decades as new aesthetic technologies have been introduced into practice.[1] A major cause of wrinkles, laxity, and cellulite is the reduction in the quantity and quality of collagen in the dermis and hypodermis.[1] The author has previously reported that near-infrared can penetrate deep into human tissue to achieve skin tightening[2–7] and that multisource, phase-controlled radiofrequency (RF) treatments provide safe and effective long-term stimulation of elastin, which is beneficial for skin rejuvenation by improving skin laxity and wrinkles.[8–14]

RF devices have also been widely used for skin tightening, and are thought to heat the dermis and subcutaneous tissues, thereby stimulating dermal collagen remodeling.[8–14] One of the effects of dermal heating is an immediate change in collagen structure, followed by long-term stimulation of neocollagenesis beginning 4 to 6 weeks after treatment.[15] These thermal effects can help reduce the appearance of wrinkles and laxity and improve contours on both the face and body.[1]

The thermal effects of monopolar and bipolar RF have demonstrated efficacy in skin tightening.[1] Nevertheless, these effects are often partial or unpredictable, due to the uncontrolled nature and possible pain produced during monopolar or unipolar RF treatments and the superficial nature of energy flow for bipolar or tripolar configurations.[1] In addition, these first-generation RF therapy systems lack the ability to adjust the delivered power based on differences in individual skin impedance.

In the author's previous research, multisource, phase-controlled RF systems with six independent RF generators were used.[8–14] Each of these generators are phase-controlled, allowing for a complex three-dimensional (3D) interaction to occur between the electromagnetic fields produced in the tissue. Since adjacent electrodes, on each side of the handpiece, posses identical polarities, no current is created between these electrodes on the skin's surface, and most of the energy is driven deeper into the skin with minimal epidermal flow.[8–14] In addition to the RF delivery technology, the tested system facilitates continuous real-time measurement of skin impedance and delivers constant energy to the patient's skin, independent of changes in its impedance.

In this study, a novel, multisource, phase-controlled RF system with four concentric electrodes specially designed to deliver focused energy was used (Figure 1) and provided both patient-reported and objective, clinical evidence of skin tightening.

METHODS

Patients. Twenty-five Japanese patients (20 women and five men) aged 27 to 72 years (mean age: 52.80±13.89 years) with Fitzpatrick Skin Types III and V were enrolled

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in this study. All of the patients had visited the Clinica Tanaka Anti-aging Center to reduce undesirable fat tissue and to seek skin tightening of the face and body. Twenty-five patients received treatment on the face, and 3 out of 25 patients were also treated on the abdomen and legs. None of the patients had a history of any type of skin disease or cosmetic procedure that affected the treatment areas. The patients did not use any specific skincare products and had no specific diet. Patients who exhibited weight loss during the study period were excluded from volumetric measurement analyses, because changes in diet and/or exercise might affect volumetric changes. After reading the experimental protocol and being advised of the treatment risks, all patients gave written informed consent for participation in the study. Informed consent to participate in the study and consent for the use of photos were received from all patients. The study followed ethical principles described in the current revision of the Declaration of Helsinki.

RF treatment. The RF device used in this study was a Mini-Shaper treatment handpiece and an EndyMed PRO™ treatment system (EndyMed Medical; Caesarea, Israel), which is a multisource, phase-controlled RF system that emits at a 1-MHz frequency at 1 to 50W. The patients' faces were treated at 25 to 30W, while the abdomen and legs were treated at 50W. If the patient reported a strong sensation of heat, scanning was performed slightly faster and/or the treatment head was moved slightly away from the point of heat sensation. The patients were treated until they experienced a burning sensation and mild erythema. No oral analgesics were administered before, during, or after the treatment. In addition, no skin cooling was required. Three to five treatment sessions with one-month intervals between treatments were performed.

The electrode surface area is 9cm^2, prompting approximately a 250-percent increase in the effective treatment area compared to the handpiece for face and neck treatments used in the author's prior studies (Figure 1). Thermal images of the Mini-Shaper RF device used in the present study showed deeper penetration and a higher temperature of 2.9 degrees at 4mm in depth compared to the handpiece used in the author's prior studies (Figure 2). A representative thermal

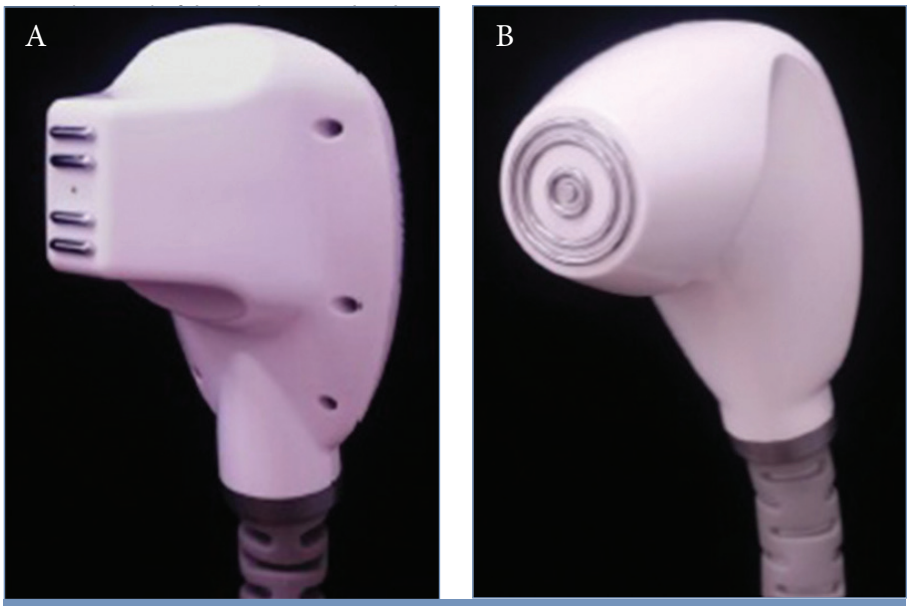

FIGURE 1. A) ENDYMED Small handpiece used in the author's previous studies, designed for treatment of the cheeks, neck, and décolleté. The handpiece is composed of four linear electrodes composing two dome-like electromagnetic fields with the same phase. Effective penetration depth is 4mm; electrodes effective surface is 3.4 cm^2. B) ENDYMED Mini-Shaper handpiece used in the study designed using four concentric electrodes creating a two-ring-shaped electromagnetic field with a similar phase. Effective penetration depth is 7mm; electrode effective surface is 9.0 cm^2.

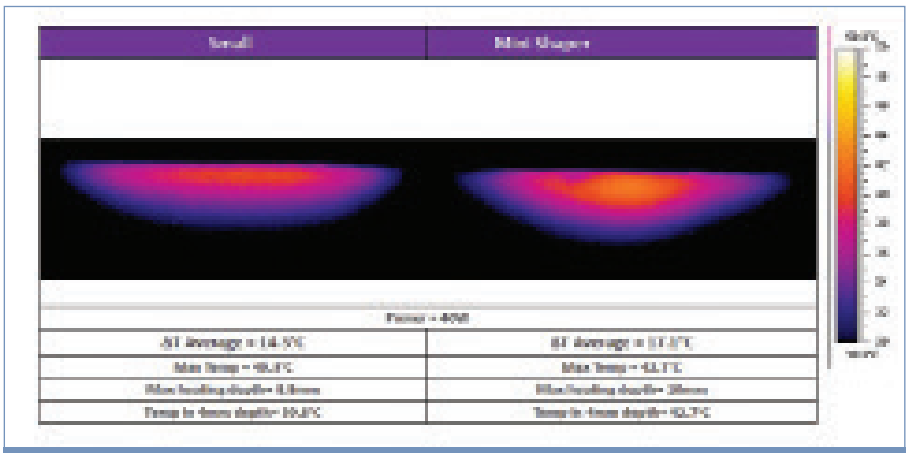

FIGURE 2. Thermal imaging (ThermaCam SC640; FLIR, Boston, Massachusetts) comparison for the ENDYMED Small and ENDYMED Mini-Shaper handpieces evaluating the thermal profile of both using continuous movement on an agar substrate, which demonstrates skin impedance. Based on thermal analysis, it can be seen that the ENDYMED Mini-Shaper penetration depth is greater compared to the ENDYMED Small, in addition to achieving higher temperatures when using the same energy level of 40W for 30 seconds.

the varying degrees of tightening in colors that range from yellow to red (red: -5mm change). Green areas indicated no changes to the face, while gray areas indicated changes of more than 5mm. Three-dimensional volumetric assessments were performed up to 12 months after the treatment.

Subjective assessments. Subjective assessments were performed using

images are presented in Figures 4, 5, and 6. Marked volumetric reduction in the treated body area can be observed in 2D color digital photographs compared to pretreatment in Figures 7 and 8. Ninety-six percent of patients reported satisfaction with the results, and all patients reported satisfaction with the convenience of the procedure (Figure 9). The mean degrees of satisfaction with the

FIGURE 3. Mild erythema and thermal imaging (FLIR E4; FLIR, Boston, Massachusetts) of a patient's jawline (A, B) and knees (C, D); the patient's jawline was treated at 33W and knees were treated at 45W.

results and convenience of the procedure based on a five-point scale from 0 to 4 points were 3.12±0.83 and 3.28±0.84, respectively. Complications were minor and transitory, consisting of a slight burning sensation and mild erythema, which resolved within one hour posttreatment. Most of the patients did not report feeling pain during the RF treatment, even though therapy was performed without anesthesia and contact cooling. Side effects, such as epidermal burns, adipose tissue atrophy, and contraction were not observed, and the patients felt comfortable throughout the study.

DISCUSSION

In our clincal experience, skin tightening procedures to improve skin laxity and contours of the face and body, regardless of age or skin type, are among the most common requests from patients. Although invasive procedures, such as liposuction or surgeries, are effective in improving contours and reducing undesirable fat tissue, the postprocedure downtime and scar formation are not desirable. Ablative procedures, such as laser resurfacing, are effective in skin tightening; however, the downtime and potential adverse effects, such as hyper- and hypopigmentation, are also not desirable. Noninvasive skin tightening procedures can be particularly applicable to skin of color, such as that of Asian patients, because such procedures are independent of skin type.[16] Whereas nonablative skin rejuvenation heats up the superficial dermis, deep tissue heating that involves RF, laser, or near-infrared sources aims to induce thermal injury in the deep tissue.[17] The aim of deep tissue heating is to stimulate new collagen formation, which can achieve skin tightening. RF treatment is capable of volumetric heating of the mid-to-deep dermis, as well as selective heating of the fibrous septa strands and fascia layer.[18] Specifically, RF energy heats hydrodermal collagen, promoting both collagen remodeling and skin tightening.[19] Clinically, these effects promote dermal collagen production and the tightening of these deep subcutaneous structures.[18] RF devices have been used in thermal delivery systems to provide the beneficial effects of heat while avoiding some of the downfalls of more standard lasers.[20]

In this study, the novel multisource phase-controlled RF system was used, which allows for continuous, real-time measurement of skin impedance and the delivery of constant energy to the patient's skin, independent of changes in its impedance. Using the multisource phase-controlled RF system, less thermal damage of the dermis and subcutaneous tissues occurs compared to during monopolar or unipolar RF treatments. The author evaluated the efficacy of the multisource, phase-controlled RF treatments both subjectively and objectively and found that the treatments provide satisfactory results without notable side effects. Furthermore, most of the patients reported being satisfied with the improvements in skin laxity and did not report feeling pain during the treatment, even though therapy was performed without anesthesia and contact cooling.

Although the volumetric measurement was performed 12 months after the final treatment, marked volumetric reduction and skin tightening were observed compared to the pretreatment volume in all of the patients. Since the effects of this RF treatments are clinically observed for at least 12 months after the treatment, further studies of volumetric assessments with a longer follow-up time periods are needed.

Side effects, such as epidermal burns, adipose tissue atrophy, and contraction were not observed, and the patients felt comfortable throughout the study. Further research is necessary to determine if a higher output, increased frequency of treatments, or longer periods of treatment can be even more effective.

Limitations. It should be noted that this was a preliminary study that included a fairly small number of patients. Moreover, we cannot exclude the possibility that lifestyle habits, such as food, alcohol, and salt intake might impact the changes observed in this study. Therefore, larger studies with longer posttreatment periods are warranted in order to evaluate variations in treatment parameters and correlations with patients' environmental factors. In addition, the lack of a control group and the lack of a comparison between dosage strengths and frequencies limit the significance of our findings.

CONCLUSION

Using multisource, phase-controlled radiofrequency treatments with a unique concentric electrode configuration, the author found significant improvements in contours and skin laxity through objective assessments, and most patients reported being satisfied with the results. The major advantage of

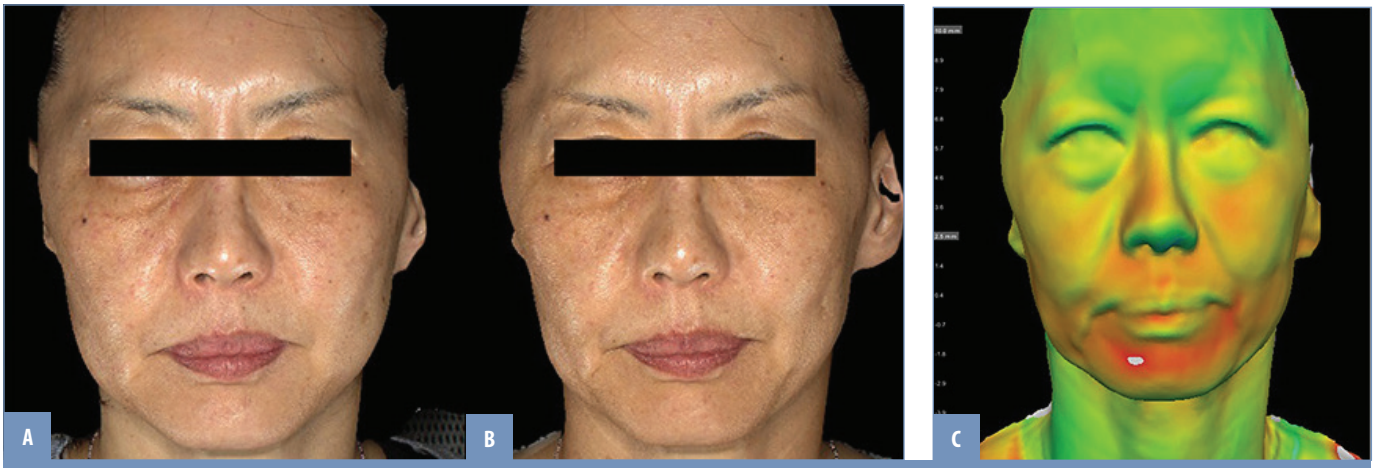

FIGURE 4. A 57-year-old Japanese woman; marked improvement of skin laxity was observed in 2D color digital photographs when comparing pretreatment (A) to posttreatment (B). Volumetric reduction in superimposed 3D volumetric assessment (C) was observed at 12 months after the third treatment when compared to the pretreatment. The varying degrees of tightening achieved are shown in colors yellow to red (red: -5mm change). Green areas indicate no changes to the face, while gray areas indicate changes over -5mm. The tightening effects on the lower two-thirds of the face as a result of the treatments lasted for 12 months.

FIGURE 5. A 57-year-old Japanese woman; marked improvement of skin laxity was observed in 2D color digital photographs when comparing pretreatment (A) to posttreatment (B). Volumetric reduction in superimposed 3D volumetric assessment (C) was observed at 12 months after the third treatment when compared to pretreatment. Tightening effects on the perioral areas as a result of the treatments lasted for 12 months.

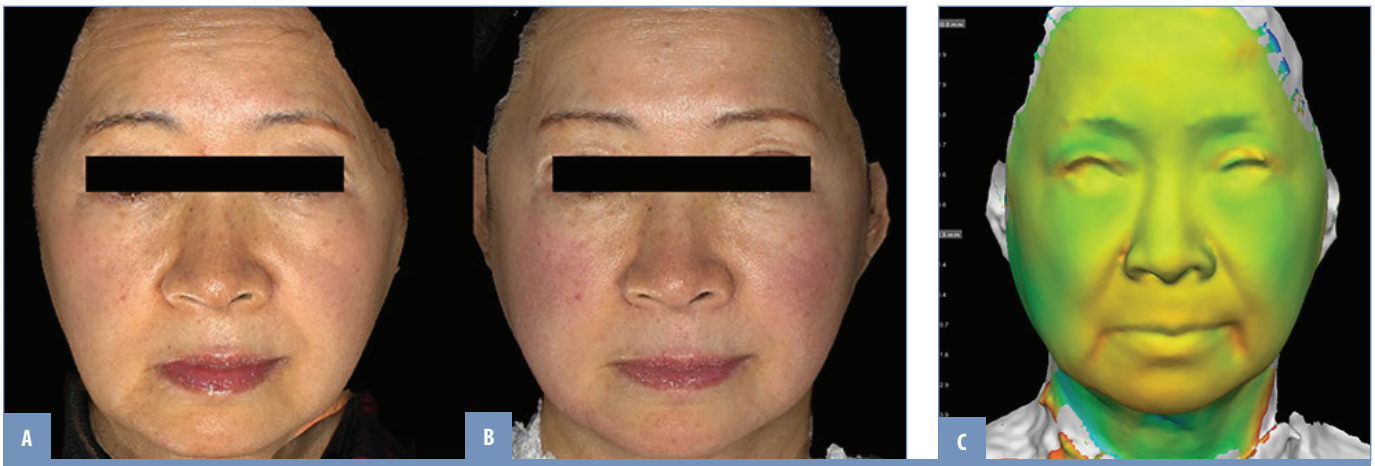

FIGURE 6. A 72-year-old Japanese woman; marked improvement of skin laxity was observed in 2D color digital photographs when comparing pretreatment (A) to posttreatment (B). Volumetric reduction in superimposed 3D volumetric assessment (C) was observed at 12 months after the third treatment when compared to pretreatment. Tightening effects on the lower one-third of the face, especially the perioral areas, as a result of the treatments lasted for 12 months.

FIGURE 7. A 27-year-old Japanese woman; marked improvement of skin laxity in the right leg was observed in 2D color digital photographs when compared to the pretreatment. Treatments were performed five times at one-month intervals. A) Pretreatment; B) six months after the fifth treatment; and C) 12 months after the fifth treatment. The tightening effects from the treatments lasted for 12 months.

the multisource phase-controlled RF system is its long-lasting efficacy. Moreover, this technique produced minimal complications and downtime, as well as few side effects. Overall, this noninvasive, multisource, phase-controlled RF approach provides safe, long-lasting, and effective treatment of skin tightening.

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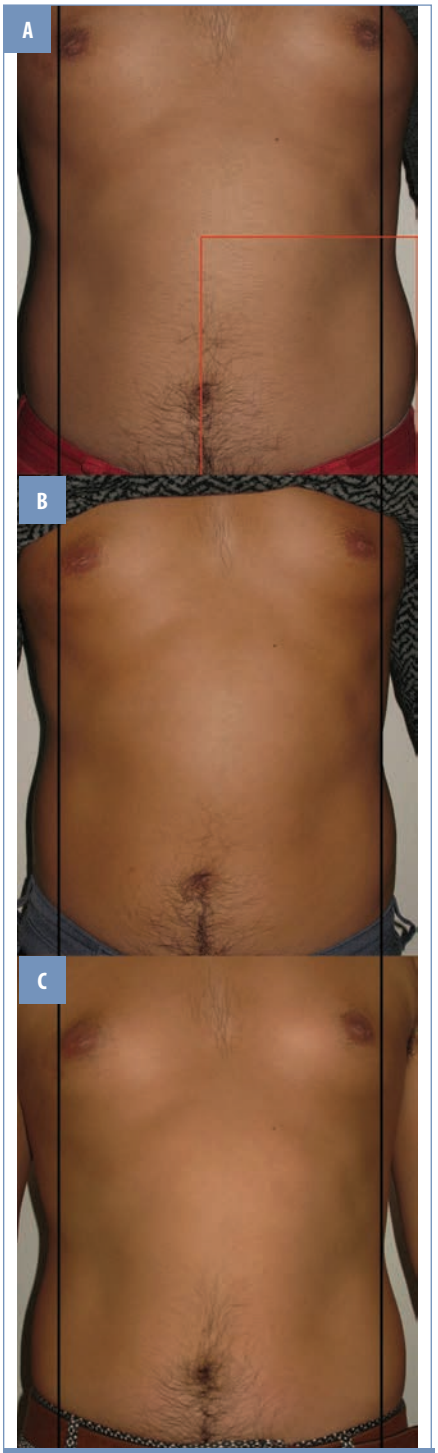

FIGURE 8. A 38-year-old Japanese man; volumetric reduction in the treated area (left abdomen, the area surrounded by a red line) was observed in 2D color digital photographs whencompared to the pretreatment. Treatments were performed three times at one-month intervals. A) Pretreatment; B) three months after the third treatment; and C) 12 months after the third treatment. Tightening effects of the the treatments lasted for 12 months.

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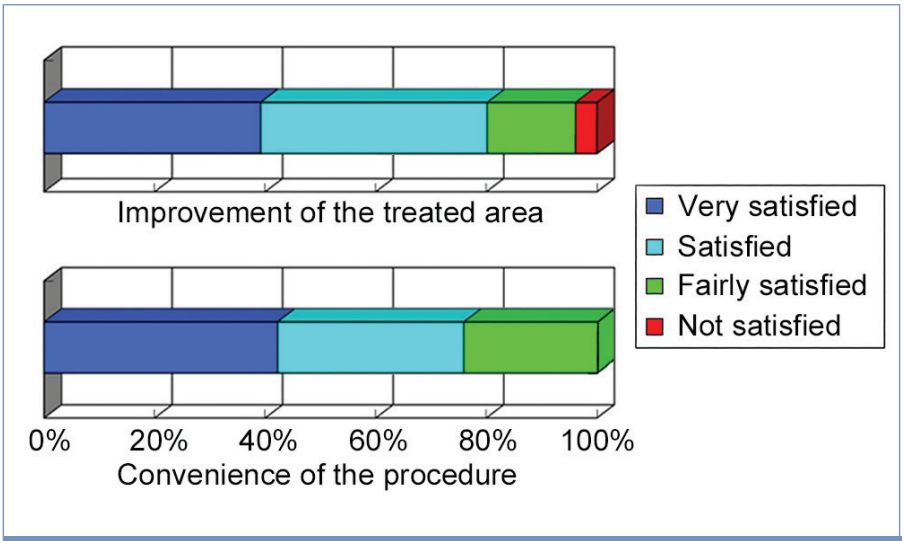

FIGURE 9. Subjective assessments were performed using questionnaire data collected at 12 months posttreatment. The patients rated their degree of satisfaction with both the improvement of the treated area and convenience of the procedure. Subjective assessments are shown as follows: very satisfied (blue), satisfied (light blue), fairly satisfied (green), and not satisfied (red).

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